

U.S.S.N. 10/688,305  
Filed: October 17, 2003  
**RESPONSE TO RESTRICTION REQUIREMENT**

**Remarks****Restriction Requirement**

In the Restriction Requirement mailed February 24, 2006, the Examiner divided the claims into three (3) groups:

Group I, claims 1-12, drawn to a method for making a biological matrix;

Group II, claims 13-17, drawn to a method for augmenting a tissue defect; and

Group III, claims 18-22 and 24-33, drawn to a biological matrix.

Claim 23 was not listed in the restriction requirement. However, since this claim defines a method for augmenting a tissue defect, Applicants will assume that claim 23 should be in Group II. In response, Applicants elect Group III, with traverse. Applicants are electing product claims such that when found allowable, the process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

As noted in MPEP Section 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent or distinct as claimed; and

(B) There would be a serious burden on the examiner if restriction is not required.

In the present case, there is no serious burden on the Examiner since the biological matrices defined by claims 18-22 and 24-33 are the only compositions that can be made and used in the methods defined by the claims in Groups I and II. Therefore, Groups I, II and III should be examined together.

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Furthermore, claim 1 links Groups I and II since claims 13-17 are dependent upon claim 1. Therefore, the method of augmenting a tissue defect in a subject is limited to biological matrices prepared by the method of claim 1. A search for the biological matrix made by the methods defined by the claims would include methods of using such matrices. It is also noted that Groups I and II are classified in the same class (i.e., 435). In addition, the living biological matrices defined by claims 18-22 and 24-33 are the only products produced by the method of Group I. In contrast to the Examiner's assertion, the biological matrix cannot be made as described by the Examiner. Claim 18 defines a living biological matrix comprising a spore-like cell, cell fragments, lipids and polysaccharides. This matrix cannot be made simply by seeding keratinocytes on a collagen scaffold or liver basement membrane, as alleged by the Examiner. Furthermore, the Examiner has provided no proof that seeding keratinocytes on a collagen scaffold or liver basement membrane would contain all of spore-like cell, cell fragments, lipids and polysaccharides. Furthermore, materially different products cannot be used to augment tissue defects as defined by the claims. Claim 23 specifically defines using the biological matrix of claim 18. As discussed above, claims 13-17 are dependent upon claim 1. Therefore, the matrix must be prepared by this method. The biological matrix prepared by the method of claim 1 would not result in a skin equivalent or a smooth muscle cell matrix, as alleged by the Examiner and the Examiner has not shown that such products are produced by this method. Therefore, Applicants request that all Groups be examined together.

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### Election of Species

The Examiner also required an election of species for Group I, claims 4-8, a cell sample; Group II, claims 14-16, a tissue defect and Group III, claims 26-31, a cell sample. In response, Applicants elect blood as the cell sample for Groups I and III and spinal cord defect as the tissue defect for Group II, with traverse. Claims 1-5, 10-13, 16-28 and 33 read on the elected species. As noted by the Examiner, claims 1, 13 and 18 are generic. Therefore, the election of species is understood to be for initial searching purposes only, and applicants expressly reserve the right to have other non-elected species examined on the allowance of a generic claim.

Applicant traverses the election of species because the generic claims do not recite such a multiplicity of species that an unduly extensive or burdensome search be necessary. In the present case a search for tissue defects would include all species recited in the claims. In addition, a search for a biological matrix containing a cell sample would include all species recited in the claims. The Examiner has not demonstrated that it would be a burden to examine all recited species.

Furthermore, the Examiner argues that cell samples and tissue defects are separate inventions and therefore the election is proper. However, this is not the legal standard for an election of species. "A requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required." (see MPEP 808.01(a)). The Examiner has not fulfilled either requirement. Therefore, Applicants request examination of all species recited in the claims.

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Examination of all of claims 1-33 is respectfully solicited.

Respectfully submitted,

  
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